Small Business Impact Questionnaire

The following questions pertain to how the changes in the Nevada Administrative Code presented in the enclosure will affect your business. If it is determined that the proposed regulation is likely to impose a direct and significant economic burden upon a small business, or directly restrict the formation, operation or expansion of a small business, then the agency will take any or all of the following actions:

1. Insofar as practicable, consult with owners and officers of affected small businesses,

2. Consider methods to reduce the impact of the proposed regulation, and

3. Prepare a small business impact statement and make copies of the statement available to the public at the workshop conducted and the public hearing held pursuant to NRS 233B.061.

Please answer each of the questions that apply and add any qualifying remarks that may help us to understand your position. **Mail, fax or scan and email your completed form so it is received by the Division on or prior to 5:00 PM on December 3, 2013** to:

Joseph Theile, Management Analyst II
Division of Public and Behavioral Health
Medical Marijuana Program
4150 Technology Way, 2nd Floor
Carson City, NV 89706
(775) 684-3487
(775) 684-5951 (fax)
jtheile@health.nv.gov

Your Name: *Dr. Rena' E. Starks, N/ESI, NIH,*
Organization: *IAMB dba TbT Group duns: 078313120*
Date: November 22, 2013

NRS 233B.0382 "Small Business defined." "Small business" means a business conducted for profit, which employs fewer than 150 full-time or part-time employees.

1. How many employees are currently employed by your business? 4
If more than 150, you will not need to answer the rest of the questions. Please MAIL, FAX or EMAIL the questionnaire to the above address. If less than 150, please continue with the remaining questions.

2. Will a specific regulation have an adverse economic effect upon your business? If so, please indicate the estimated dollar amount(s) you believe the adopted regulations will cost you over one calendar year with a brief explanation as to how the dollar amount was calculated.

Millions will be diverted, lost efforts, economic downfall, loss, and waste of time that is exhaustive but, being invested:

✓ **Yes** _____ No Explain: Please list each regulation and explain the impact.
The list of regulations as it is presented stifles the economy, stops progress of the NIH systems, continues to allow great research out of this Country, and if implemented could cause a line to be drawn in the sand by the DEA v. State. This method will encourage human danger? It will be discriminatory? It will not be a good answer that will safely continue the business of Medicine being defined. We all recognize Gonzales v. Raich concludes, "the State does have a right to purport the crimes," AS WELL, the DEA has discretion to take out illegal businesses. Why not compromise by education to accept a franchise-able businesses that allows all small business concerns, to become involved by proper license and access, ie., TbT Group, Inc., which will show clinical trials and studies to support www.theiamb.com, and this will allow the big businesses to come on board to gain NIH Standards to medicine? This would be one idea to grow the economy and satisfy all?

IMPACT:
Therefore, the thought of TbT Group franchising to help Veterans, VA Directives, Investors, Manufacturers, Developers, DEA, Distributors, NIH, and the common business person who wants in or to become involved in this business is unattainable by these set of Regulatory Method, when, we all too well know that "the feds own the meds" and clinical trials grants all access, so we should as those with clinical business on our minds relate to the standards of collaboration.

DEA Registration lists 111 businesses with a right to do business, by proper access to licenses.
TbT Group had plans of education symposiums to help all learn how to transition their weed business, to a federal level of safety.
The theory of TbT Group would be to open the franchising to the Veterans who cannot stand a chance against big industry dollars, grant accessibility by others, b

3. Will the regulation(s) have any beneficial effect upon your business? If so, please include any cost savings you believe the adopted regulations will save you over one calendar year with an estimated dollar amount if applicable.

✓ **Yes** _____ No

Explain: NEGATIVE IMPACT, the right regulatory businesses that will increase fed activities, jobs, and add to the State levels are going to have to compete with shady businesses like, Dr. Reefer, those who care about the dollar and not about the patients or their care, or free medicine, or the businesses that that activity brings.

4. Do you anticipate any indirect adverse effects upon your business?

✓ **Yes** _____ No

Explain: As advocates on behalf of the federal government, we seem foolish if we believe in other methods other than the sciences? Therefore, we believe and know that all activity does have a doorway that is open for green business, if we do this right? We can involve all, but, the pattern must be with a better access to control and in this greedy affair, this TbT will, be the only answer sent that will be inclusively a way for all who can afford to become involved and immediately open offices, and this will allow those with much funding to also do their businesses.

5. Do you anticipate any indirect beneficial effects upon your business?

✓ **Yes** _____ No

Explain: NO BENEFITS, much disaster, for our project is like the gorilla in the room, everyone knows that it is here, but, no one wants to deal with it, logically?

Department of Justice
Drug Enforcement Administration

FAX Transmittal Sheet for UNCLASSIFIED Information Only

1 03 / 11 / 2013
Transmission Date (MM/DD/YYYY)

2 Number of pages being transmitted (Including this transmittal sheet) 2

3 **TO:** FAX FTS #:

FAX COMMERCIAL #: 877-237-9662

NAME: Rene Starks

PHONE: 530-324-2333

OFFICE/ORG:

4 **FROM:** FAX FTS #:

FAX COMMERCIAL #: 202-353-1487

NAME: Yvette Holliday, Program Analyst

PHONE: 202-353-1048

OFFICE/ORG: Drug Enforcement Administration

5 Additional Comments

Note. If you have any problems with this transmission (incorrect number of pages/poor quality), call the sender and request retransmission.

U.S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Registration and Program Support Section

Washington, D.C. 22152

Dear Registrant:

If you are applying for registration as Schedule I Researcher or K-9 Dog Handler, you must submit an original and 3 copies of a research protocol.

Please follow the outline listed below:

Schedule I Researcher
(You must complete items numbered 1-7)

Researcher/K-9 Dog Handler
(You must complete items numbered 2, 3, 4, 6, & 7)

1. INVESTIGATORS. The protocol must reflect the name, address, institutional affliction (if appropriate), and qualifications, to include both a curriculum vitae and bibliography of each investigator in the research project.

2. PURPOSE. The protocol must contain a brief description of the purpose of the project.

3. SUBSTANCES. The protocol must reflect the name and amount of each Schedule I substance to be utilized in the project.

4. PROJECT. The protocol must contain a description of the research project, to include the location at which the research will be conducted, the duration of the project, and how the controlled substances will be used.

5. LIVE SUBJECTS: If live research subjects will be used, the protocol must reflect the number and species of research subjects, the dosage of controlled substances to be administered, and the route and method of administration to be used.

6. SECURITY. The protocol must contain a description of the security measures to be applied, including where and how the controlled substances will be stored, and who will have access to them.

7. RECORDS. The protocol must contain a description of the proposed recordkeeping system documenting receipt and disposition of the controlled substances and the name of who will maintain the records.

If you have any further questions, please call 202-307-7251 or visit our website at www.DEAdiversion@usdoj.gov

DATE:_____
INITIAL:_____

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

JUL 1 4 2010

Rena E. Starks
7501 Royal Crystal Street
Las Vegas, Nevada 89149

Dear Ms. Starks:

This responds to your e-mails sent to the Diversion Group Supervisor Jayne Tomko-Griffin, Las Vegas District Office, Drug Enforcement Administration (DEA) on March 1, 2010, and February 25, 2010. Your inquiry was forwarded to the Office of Diversion Control, Liaison and Policy Section, for a response. In your e-mails, you requested an "opinion letter" regarding the "TBT Group Project" related to marijuana.

Please be advised that DEA may not provide private entities with legal advice or opinions on an individual basis. Under the Administrative Procedure Act (APA), federal agencies are required to make available to the public, through publication in the Federal Register, substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated or adopted by the agency. Adherence to this APA requirement ensures fairness to all members of the public by avoiding having the agency provide legal guidance to certain individuals to the exclusion of others. Accordingly, our response to your inquiry must be limited to reiterating the pertinent provisions of the law, regulations, federal court decisions, or other publicly disseminated documents issued by the agency.

It appears that your proposal is intended to provide marijuana for human consumption outside of FDA-approved, DEA-registered research settings. If so, please note that, under federal law, as set forth in the Controlled Substances Act (CSA), marijuana remains a schedule I controlled substance. Because of this, human use of marijuana outside the confines of an FDA-approved, DEA-registered research project is prohibited, as the United States Supreme Court has made clear. *United States v. Oakland Cannabis Buyers' Cooperative,* 532 U.S. 483, 491 (2001). The Supreme Court also made clear that in the *Oakland Cannabis Buyers' Cooperative* case, as well as in *Gonzales v. Raich*, 541 U.S. 1 (2005), that marijuana cultivation and distribution for claimed "medical" use remains illegal under the CSA, even in those states that have enacted laws purporting to make such activities permissible.

Sincerely,

Mark W. Caverly, Chief
Liaison and Policy Section
Office of Diversion Control

GARY D. LEITZELL
MAYOR

CITY of DAYTON, OHIO
OFFICE OF THE CITY COMMISSION
101 WEST THIRD STREET • P.O. BOX 22 • DAYTON, OHIO 45401
CITY HALL • (937) 333-3636

To Whom it may concern,

June 12, 2013

I would like to send this Letter of Support for The Betterment and Empowerment through Education and Entertainment, the BEEE Group, Inc., the International Association of Mortgage Brokers, Inc., and the International Association of Medicine Backers, Inc., and Simonton Genesis Ministries, Inc., the first ~~federal~~ bundling compliance group.

Each City is going through economic crisis and I have taken the time to become educated to see that these are projects, services, and products that deserve to be recognized, supported and encouraged.

This compliant federal bundle of non profits, paying for profits, hiring Veterans, crosses all lines of the government. I see the financial, eco-socio advantage to this bundle as it sets new standards and represents projects covering children, medicine, gang issues, drowning, health, fatherhood, family, food, and much more. This project creates jobs, is sustainable, and it has an impact.

Sincerely,

Gary D. Leitzell

Modernizing the Regulation of Clinical Trials and Approaches to Good Clinical Practice
Part 15 Public Hearing

April 23, 2012

FDA White Oak Campus
10903 New Hampshire Ave, Building 31, Room 1503
Silver Spring, Maryland 20993

Each speaker will have 15 minutes for their presentation. There will be 5 minutes following each presentation to offer an opportunity for the panel to ask clarifying questions.

April 23, 2012 Presentations

8:30 – 8:40 am **Presiding Officer Opening Remarks**

Kathleen Uhl, MD
Deputy Director, Office of Medical Policy
Center for Drug Evaluation and Research

8:40 – 8:55 am (8:55 – 9:00 am)

Marta Fields, *Seattle Genetics*

9:00 – 9:45 am (9:45 – 9:55 am)

The Association of Clinical Research Professionals

Gary Shangold, *Convivotech, LLC.* (9:00-9:15)

Michael Koren, *Jacksonville Center for Clinical Research* (9:15 – 9:30)

Jennifer Holcomb, *Duke University* (9:30 – 9:45)

9:55 – 10:10 am (10:10 – 10:15 am)

Jules Mitchel, *Target Health, Inc.*

BREAK

10:15 – 10:30 am

10:30 – 10:45 am (10:45 – 10:50 am)

Jennifer Kerr, *MED Institute, Inc.*

10:50 – 11:05 am (11:05 – 11:10 am)

Cami Gearhart, *Consortium of Independent Review Boards (CIRB)*

11:10 – 11:25 am (11:25 – 11:30 am)

Lowell Schnipper, *American Society of Clinical Oncology*

11:30 – 11:45 am (11:45 – 11:50 am)

Andreas Koester, *Janssen Pharmaceutical Companies*

LUNCH **Ala Carte items will be available for purchase on site**

11:50 am – 12:50 pm

12:50 – 1:05 pm (1:05 – 1:10 pm)

Lynn Huynh, *Johns Hopkins Bloomberg School of Public Health*

1:10 – 1:25 pm (1:25 – 1:30 pm)

Anton Lewis Usala, *CTMG, Inc.*

1:30 – 1:45 pm (1:45 – 1:50 pm)

Royce Heslep, *Aptia Systems, Inc.*

1:50 – 2:05 pm (2:05 – 2:10 pm)

Matthew Weinberg, *The Weinberg Group, Inc.*

BREAK

2:10 – 2:25 pm

2:25 – 2:40 pm (2:40 – 2:45 pm)

Rene Cabral-Daniels, *National Patient Advocate Foundation*

2:45 – 3:00 pm (3:00 – 3:05 pm)

Ramita Tandon, *Parexel International*

3:05 – 3:20 pm (3:20 – 3:25 pm)

Rena Starks, *Super Admin*

3:25 – 3:40 pm (3:40 – 3:45 pm)

Douglas Peddicord, *Association of Clinical Research Organizations*

Open Public Comments

3:45 – 04:15 pm

Closing remarks/Adjournment

04:15 – 04:30

Please be advised that as soon as the transcript is available, it will be accessible at http://www.fda.gov/Drugs/NewsEvents/ucm284118.htm.

Written and electronic comments will be accepted until May 31, 2012. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov.

Acquiring a TbT Project Franchise ~ "GREEN CREATE JOB"

Veterans and New Graduates will be given top priority for collaborations.

Most Owners/Operators enter into our system by having their own building, patient/client base, or a professional knowledge about how to build their system for success, with little assistance for compliance to lead to the modernization efforts and mission for good clinical practices.

Here is your opportunity to have a turn key operation for minimal costs that will put you in the business of servicing others, within meeting compliance.

TbT Group is listed on www.SAM.gov duns: 078313120 and has all requirements to offer a grants team to those who affiliate in order to help grow our services.

We offer safe, success, that if you do have a medical background that offer many benefits by learning the NIH way!

Financial Requirements/Down Payment

An Initial down payment is required when you establish a new clinic 20% of the total cost, $5,000, plus an additional non refundable $2,500 for admin fees. If you do not have an existing clinic to convert 10% down payment, plus an additional non refundable $2,500 for admin fees.

The total cost of set business to licensing will be $55,000, which will only be the partnership. Candidates must pay for DEA licenses and Clinic or Office set up, attorney fees if applicable, separately.

An additional cost of $2,500 for training, guidance to compliance, software for reporting, and the training and set up software costs for contracts, this is non refundable and is **not** a part of the down payment to open an clinic.

TbT Group does not offer financing, but, TbT Group does refer: **Small Business Administration EDVOSB/M,** news@updates.sba.gov Veterans, have a preference right now with boots to business campaign.

Ongoing Fees

IAMB dba TbT Group has all require, Eco-Socio, Disadvantaged, Minority, Female of Small business, we can also offer Faith Based and Veteran Owned, this is some of the benefits that will be shared in status to you to gift advantages as you invest in your future careers.

During the term of franchise and because of the low "in" and turnkey expense of documentation to set up TbT Group will gain 60% of this for profit business from each franchise owner. TbT will not pay for any costs to do business but, will educate, license, and guide the franchise holder for income after all cost to do business that is complete for the affiliation for federal backing and use of all services, and initial set up.

Yearly independent audits for business renewals will be in effect for compliance.

As per the United States Department of Justice guidance will lead to the **disclaimer**: If you are unfamiliar with the market you invest, ***DO NOT INVEST***. NON COMPETES are in effect as well as confidentiality.

Compliance

This is a FEDERAL INITIATIVE to clinically introduce new drugs under strict education and confidentiality.

FAQ's

What does this involve?

Serving to reporting to the federal government that will help to move all Schedule 1 drugs by the science of medicine changing the facts to proper categories to benefit the patients we serve.

How much income can I make?

Profitability depends on one factor and it is most important, your ability to operate the business effectively.

Is there an opportunity to acquire more than one facility?

TbT is an equal opportunity franchise project by choice; therefore, Candidates who have successfully attained, maintained, to operate multiple businesses may be suited to operating several TbT Group Project franchises.

How can I become a non U.S. TbT Group Project?

Decisions relating to the selection of Veteran candidates are made locally and by a Research management team in the country where the Project is to be located. For interest in specific markets regarding international franchising, please contact 2Cliniciamb@Gmail.com.

As per the United States Department of Justice guidance will lead to the **disclaimer**: If you are unfamiliar with the market you invest, ***DO NOT INVEST***. NON COMPETES are in effect as well as confidentiality.